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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,131	11/30/2001	Daniel R. Soppet	PZ037P1C1	3384

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,131	SOPPET ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *040105*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 4/1/05, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-74 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth previously. Applicant argues that the specification teaches the polypeptide and polynucleotide " may be also used as an agent for immunological disorders including arthritis, asthma, immune deficiency diseases such as AIDS, leukemia, rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, sepsis, acne, and psoriasis. And that a role for the polypeptide in immunity has been confirmed by Sui et al. This argument has been fully considered but not deemed persuasive. As set forth previously, a stated belief that a correlation exists between the polypeptides and any number of disparate diseases is not sufficient guidance to use the claimed polynucleotides to treat and/or diagnosis a particular disease; it merely defines

a starting point for further research and investigation. One skilled in the art appreciates that such vague teachings and suggestions provided by the specification do not provide a particular assertion that can be the bases of a substantial utility. The hypothesis that the polypeptide may be involved in immunity cannot be the bases of a substantial utility. One skilled in the art appreciates that the mammalian immune system is one of the most complex systems in the known universe, e.g. in the opening chapter of the textbook Immunology the author states the immune system is a "network whose complexity rivals that of the nervous system", see page 1 of Kirby, J. Immunology 1992. Simply suggesting or asserting that a polypeptide with no known function *may* be involved in some way in the immune system does not provide a use for the polypeptide, other than as an object of further research to try to find what activities the polypeptide might have.

Applicant argues that the polypeptide and polynucleotide can be used as markers for lymphoid cell types. This argument has been fully considered but not deemed persuasive. As set forth previously, most every polypeptide and polynucleotide exhibits some tissue specific pattern of expression. However, without some assertion that the tissue or chromosomal localization can be used to practice a particular substantial utility, as in a marker for a particular disease state, the use of the polypeptides or polynucleotides as a tissue or chromosomal marker does not constitute a substantial utility, as consistent with current examination guidelines.

Applicant's arguments regarding therapy using cell specific depletion and targeting have been fully considered but not deemed persuasive. There is no evidence in the prior art, the instant specification, or post filing date art that the instant polypeptide can be used for any therapy. There is no teaching or expectation recognized in the art that would lead one to believe

that because a polypeptide is expressed on the surface of a lymphoid cell, than it can be used in the diagnosis and/or treatment of the disorders listed by Applicant.

Claims 25-74 also stand rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

Also, as set forth previously, the claims encompass polypeptide variants of the polypeptide of SEQ ID NO: 65, i.e. substitutions, deletions or insertions in a protein corresponding to SEQ ID NO: 65; should Applicant establish a specific and substantial utility for the claimed polynucleotides, Applicant has not provided sufficient guidance as to how to make and use the encoded polypeptides which are not 100% identical to the polypeptide of SEQ ID NO: 65, but which still retain a desired property of the polypeptide of SEQ ID NO: 65.

Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above.

Applicant argues that at the time of filing it was routine to make and screen variants for activity. This argument has been fully considered but not deemed persuasive for the reasons enumerated in the body of the rejection. Further, the specification has not taught what particular activity to screen for. Applicant argues that the specification teaches uses of the claimed variants that do not require retention of biological activity, e.g. as an immunogen. This argument has

been fully considered but not deemed persuasive for the reasons enumerated in the body of the rejection, see Alexander et al.

Applicant argues that the artisan could readily envision every polypeptide that is at least 90% identical to SEQ ID NO: 65. This argument has been fully considered but not deemed persuasive. One of skill in the art appreciates that the number of possible sequences having 10 amino acid substitutions relative to a 100 amino acid reference sequence is approximately 1.1×10^{26}. Additionally, 35 U.S.C. § 112 requires the specification teach how to use the invention. The instant specification clearly fails to teach how to use variants that have no known activity.

Claims 25-74 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the skilled artisan could readily envision any number of polypeptide variants that would comprise, e.g., 5-10 substitutions, deletions or insertions in a protein corresponding to SEQ ID NO: 65 - which would constitute a substantial portion of the genus, and thus applicant was in possession of the claimed genus as defined by the courts. This argument has been fully considered but not deemed persuasive. The specification has not provided a particular essential feature, either a functional or structural feature, that the claimed genus of polypeptides possess. The recitation of a percent identity to SEQ ID NO: 65 provides no description of any amino acid sequence other that of SEQ ID NO: 65. The specification has not defined what particular common structural or functional properties are possessed by the

claimed genus of polypeptides. Further, one skilled in the art appreciates that simply writing down or verbalizing that a polypeptide should have some property does not put one in possession of such a polypeptide. Thus, one of skill in the art would appreciate that Applicant was not in possession of the claimed genus of polypeptides at the time of filing.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-

0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

June 27, 2005

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600